

Docket No.: 22841-015

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

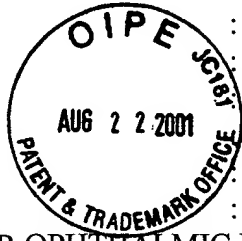
In re Application of

NICOLSON et al.

Serial No.: 09/640,526

Filed: August 17, 2000

For: EXTENDED WEAR OPHTHALMIC LENS



Group Art Unit: 1714

Examiner: V. Jagannathan

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**INFORMATION DISCLOSURE STATEMENT-F, G, H**

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. It is respectfully requested that the documents be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

In accordance with 37 CFR 1.17(p), please charge the fee of \$180.00 to Deposit Account No. 50014.

The documents listed in this IDS were produced to Bausch & Lomb (B&L) during a patent infringement litigation styled: *CIBA Vision Corporation v. Bausch and Lomb, Incorporated*, U.S. District Court for the Northern District of Georgia, Gainesville Division, Docket Civil No. 2:99-CV-034-WCO, filed March 8, 1999. The Patent Owner submits these documents for completeness of the record, along with the following description of the particular documents.

## **TABLE OF CONTENTS**

### **PCT WO 94/15980**

This B&L document by McGee and Valint mentions employing various modifying agents to achieve desired physical, visco-elastic and/or physiological properties such as strength, modulus, and various surface properties. See pp 2, 3. It is believed that by these statements the inventors make reference to agents added to the bulk, impacting surface properties, and set forth a strategy pursued by B&L to achieve a monolith.

See also, U.S. Patent No. 5,387,663, which appears to be the U.S. Patent equivalent to this PCT application.

### **EP 0295947**

This patent discloses the surface modification of rigid contact lenses to make them hydrophilic (Abstract and specifics on p 9, lines 34 et seq.)

### **Cancellation of the Boundary and Edge Effects by Choice of Lens Thickness during Oxygen Permeability Measurement of Contact Lens by Weissmann**

This is an Article on polarographic determination of Dk which criticizes the use of measurement of films instead of lenses for predicting Dk of lenses as they are only a simulation. See p 267.

### **A Study of the Complications Induced by Conventional and Disposable Contact Lenses by Hamano et al.;**

**The Impact of Overnight Wear on the Risk of Contact Lens - Associated Ulcerative Keratitis by Schein et al.;**

**The Hospitalized Cases of Contact Lens Induced Keratitis in Sweden and their Relation to Lens Type and Wear Schedule: Results of a Three-Year Retrospective Study by Nilsson et al.;**

**Corneal Ulcers in Patients with Disposable Extended-Wear Contact Lenses by Goyal et al.;**

**The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact Lenses, Schein et al.;**

**Testing Hypotheses for Risk Factors for Contact Lens-Associated Infectious Keratitis in an Animal Model by Solomon et al.;**

**Complications and Symptoms in Disposable Extended Wear Lenses Compared with Conventional Soft Daily Wear and Soft Extended Wear Lenses by Poggio, et al.;**

**"The Incidence of Ulcerative Keratitis Among Users of Daily Wear and Extended-Wear Soft Contact Lenses", The New England Journal of Medicine, Vol. 321, pp. 779-783, by Poggio et al.;**

**Corneal Ulcer and Adverse Reaction Rates in Premarket Contact Lens Studies by MacRae et al.;**

**The Relation between Contact Lens Oxygen Transmissibility and Binding of Pseudomonas aeruginosa to the Cornea after Overnight Wear by Imayasu, et al.; and**

**Novel Polyurethane-Silicone Hydrogeis by Lai.**

**"Extended Wear of Hydrogel Lenses", Problems in Optometry, Vol. 2, pp. 599-622, by Grant et al.,**

All of these references discuss the problems associated with extended wear lenses derived from conventional hydrogel polymers.

**Extended Wear in Perspective by Brennan et al.**

This article by Brennan, Coles addresses the future of new materials in extended wear.

**Coulmetrically Determined Oxygen Flux and Resultant Dk of Commercially Available Contact Lenses by Winterton et al.;**

**Coulometrically Determined Oxygen Flux and Resultant Dk of Commerically Available Contact Lenses by Winterton;**

**The Dk Project: An Interlaboratory Comparison of Dk/L Measurements by Holden et al.;**

**Coulometric Method for Measuring Oxygen Flux and Dk of Contact Lenses and Lens Materials by Winterton et al.; and**

**Oxygen Permeability of a New Type of High Dk Soft Contact Lens Material by Alvord et al.**

These references discuss the utility of the coulometric technique for the determination of reliable Dk values and, in particular, for high Dk contact lenses.

**Critical Oxygen Levels to Avoid Corneal Edema for Daily and Extended Wear Contact Lenses by Holden and Mertz,**

This "landmark" article first expresses the oxygen transmissibility requirements to meet the needs of the human cornea (minimum Dk/t required to achieve no overnight corneal swelling greater than that experienced when no lens is worn).

**Morphology Requirements for On-Eye Mobility of Soft Oxygen Permeable Contact Lenses by Domschke**

Dr. Domschke is one of the inventors on the "Jump" patents discussing the requisite morphology for silicone hydrogel contact lenses to permit on eye movement.

**Kirk Othmer Encyclopedia Of Chemical Technology (chapter on contact lenses)**

This document provides general background information on contact lenses.

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No representation is made or intended that more relevant information does not exist or that the order of presentation of the information in any way reflects their relative pertinence.

Respectfully submitted,

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